Remarks

This REPLY is in response to a Final Office Action mailed June 2, 2009. Claims 1-6 and 8-23 are pending and stand rejected.

For the reasons set forth more fully below, Applicants respectfully submit that the rejections under 35 U.S.C. §103(a) are improper, that the finality of the rejection is also improper, and urge the Examiner to withdraw the rejections and the finality and to issue a Notice of Allowance.

Priority Claim:

The Examiner denied the claim of priority of the current application to the prior-filed provisional patent application, asserting "neither the drawings nor the specification of Provisional Application No: 60/403/756, filed August 15, 2002, provides support for a combined Class A/Class B output having greater accuracy than either Class A or Class B outputs individually, as in amended claims 1 and 2, filed 02/06/2009."

Applicants respectfully disagree, because the priority Provisional application (the "756" application) does support the claim as currently pending. In particular, the "combined Class A/Class B output having greater accuracy than either Class A or Class B outputs individually" is disclosed in both the priority application and in the instant application. The limitation is supported at least in the 756 application at FIGs. 3 and 4, which are identical to FIGs. 3 and 4 of the instant application, whose filing date is August 15, 2003 (the International Filing Date). Further, both the 756 application and the instant application discloses the following:

> Using IPI as a single prediction factor and a Bayesian classifier gives a prediction accuracy of 73.2% using gene expression data and an EFuNN classifier gives an accuracy of 78.5%. The combined model accuracy, for $\beta1 = \beta2 = 0.75$ and $\alpha = 0.4$, gives an overall accuracy of 87.5%.
> 756 application, page 5, and paragraph [0092] of the instant application as published.

Further:

> Let us assume that each of the three modules produces different prognostic accuracy as follows: module one – 90% (88 and 92 for each class); module two – 70% (65 and 75 for each class respectively) and module 3 – 80% (75% and 85% for each class respectively). By using a combined output at a higher-level decision module for the final prognostic evaluation, the total accuracy increases to 92% as explained below. Page 6 of the 745 application and paragraph [0098] of the instant application as published

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These points were included in the Declaration of Nikola Kasabov (the "Kasabov Declaration") in the prior REPLY. Paragraph 15 of the Kasabov Declaration drew attention to page 14 of the published application. Paragraph 16 of the Kasabov Declaration reiterated the point made above with reference to the disclosure on page 5 of the 756 application. Paragraphs 16 through 19 reiterate the data and conclusions above relating to page 6 of the 756 application. Additionally, the Kasabov Declaration noted the conclusions to be drawn from FIGs 3 and 4 of the instant application, which, as noted above are identical in the priority 756 application. Because the Examiner did not challenge the contents of the Kasabov Declaration on these points, Applicants believe that the evidence for claiming priority to the 756 application's improved "combined accuracy" is unchallenged and therefore should be accepted.

Applicants therefore respectfully submit that the priority US Provisional Patent Application No: 60/403,756 fully supports Claims 1, 3, and 23 of the instant application, and requests the Examiner to grant priority of the instant application to US 60/403,756.

Declaration

The Examiner held that the Kasabov Declaration was considered but is moot in light of the new grounds for rejection. Office Action page 2. (See comments below). However, Applicants note that the Examiner has provided no evidence in rebuttal. Therefore, Applicants consider the Kasabov Declaration to be uncontested.

Information Disclosure Statement

The Examiner stated that the Information Disclosure Statement filed 04/13/2009 "fails to comply with 37 C.F.R. 1.98(2), which requires a legible copy of each cited foreign patent document, each non-patent literature publication ..." Office Action page 2.

In the IDS filed April 13, 2009, Applicants cited three PCT Publications, each in English, one non-patent publication in English and a Supplementary European Search Report (in English). Applicants have reviewed the non-patent publication and respectfully submit that the non-patent publication, Nikola Kasabov, IEEE Transactions on Fuzzy Systems Vol. 10 No.2, April 2002, was the best available copy. Further, Applicants submit that the article is legible.

Therefore, Applicants respectfully submit that the IDS filed April 13, 2009 should be entered.

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Withdrawn Rejections

Applicants appreciate the Examiner's withdrawal of the rejections under 35 U.S.C. 101 and 103(a) over Downs in view of Barnhill and Hemstreet. Applicants consider these withdrawals as reflecting admissions by the Examiner that the prior rejections have been overcome. In particular, Applicants believe that with the withdrawal of the prior rejections, that the Applicants' arguments relating to Downs, Barnhill and Hemstreet have been accepted, and there is no explicit or implicit teachings of all the limitations of Applicant's claim.

Rejections Under 35 U.S.C. §103

According to 35 U.C.S. §103(a), "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the **subject matter as a whole** would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." [Emphasis added.]

Thus, to maintain a rejection for obviousness, all elements or limitations of the claims must be taught, either explicitly or inherently, by the prior art. Applicants respectfully submit that the prior art has not taught all limitations of the claims, either explicitly or inherently.

MPEP 2141 states in part: "Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103. 35 U.S.C. 132 requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed. Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability."

MPEP 2142 states in part: "[t]he examiner bears the initial burden of **factually** supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to *>render obvious< the claimed invention.

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Merely conclusory statements do not meet the above standard, which requires that the Examienr "factually" supports any prima facie conclusion of obviousness.

Applicants respectfully submit that the rejections are based on simple conclusory statements by the Examiner that fall short of the required by the MPEP and the Patent Act.

Therefore, Applicants submit that the Examiner has not articulated a proper rejection under 35 U.S.C. §103(a), and that the rejections are therefore improper.

Further, because the rejections are improper, and because there are no "new grounds" for obviousness presented, the finality of the rejection is improper and should be withdrawn.

Claims 1-6 and 8-23 stand rejected under 35 U.S.C. §103 as obvious over Sharpe et al, in view of Barnhill et al. and Kasabov (PCT/NZ01/00059; "Kasabov") in view of Wu. Office Action page 3.

Applicants respectfully submit that this rejection is not a "new ground for rejection." Rather, the grounds for rejection remain the same (35 U.S.C. 103(a)), and the rejections are based on the same allegations as in the prior Office Action. Applicants respectfully submit that the newly cited art in the current Office Action, namely Sharpe and Kasabov are merely cumulative. Further, Applicants respectfully submit that the required "reasoned statement" supporting the rejections is not presented in the Office Action. Rather, the Examiner points generally to the references without a precise description of just how the portions of the references render the claims obvious.

Further, Applicants submit that Wu is not prior art at all. The effective filing date of the instant application is the date of filing of the PCT International Application, which is August 14, 2003. Because Wu was published in 2004, Wu cannot be prior art.

Applicants respectfully submit that the combination of Sharpe, Barnhill and Kasabov together do not provide an enabled system or method for making medical decisions wherein "combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually" as in amended Claims 1, 3 and 23.

Applicants provided in the prior REPLY a Declaration under 37 C.F.R. 1.132 by Dr. Nikola Kirilov Kasabov in support of the application ("Kasabov Declaration"), incorporated herein fully by reference.

Sharpe

In maintaining the rejection, the Examiner stated: "Sharpe does not specifically teach combined equations for Class A, Class B, and Class A/Class B with greater accuracy than either Class A or Class B, as in claims 1, 3, and 23." Office Action page 4. Further, the Examiner stated: "Sharpe does not specifically teach connection weight values for beta 1, beta 2, and alpha, as in claims 1, 3, and 23. However, it would have been

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obvious to one of ordinary skill in the art to substitute connection weights using any desired mathematical variable with predictable results, since this an arbitrary design parameter." Office Action page 5.

In response, Applicants respectfully submit that even if selection of connection weights were arbitrary "design parameters," that the lack of any disclosure or teaching in Sharpe of "combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually", as in claims 1, 3, and 23 as admitted by the Examiner, that the selection of connection weights by themselves, could not render Applicants' claims obvious.

Barnhill

The Examiner cited to portions of Barnhill asserted to render Applicants' claims obvious (Office Action, page 5). However, none of the cited portions of Barnhill provide a specific, enabled disclosure of how to produce an output where "combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually" as in claims 1, 3, and 23. Further, the Examiner does not provide a reasoned statement including a rationale of how a person of ordinary skill would combine the teachings to arrive at Applicants' invention as claimed.

Applicants respectfully submit that the portions of Barnhill cited are general descriptions of what might be achievable, but at most represent an invitation to invent, but do not provide any enabled methods or systems for improving the accuracy of a "combined Class A/Class B output" as currently claimed.

The Kasabov Declaration provides the following evidence: "[b]arnhill is a US patent that presents discussion of general approaches and desired results, but **does not provide any descriptions of actual methods to be used or examples of outcomes achieved using those methods to provide increased accuracy of a combined outcome prediction compared to the accuracy of individual outcomes.**" Kasabov Declaration, paragraph 11; emphasis added.

Kasabov

Applicants respectfully submit that the prior PCT publication of Kasabov does not disclose a method for providing predicting a medical outcome wherein "the error of Combined Class A/Class B output is minimized and said combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually."

The Examiner stated: "An error minimization scheme is presented in order to achieve better prediction accuracy [p. 19, lines 5-32]." Office Action page 5, third paragraph.

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Applicants respectfully submit that this portion of Kasabov addresses the error of "**a neural network module on a next new input vector**." Page 19, line 7; Emphasis added. Applicants submit that this type of error calculation refers to an error of **one class of information**. Additionally, the remainder of the cited portion of Kasabov addresses improving accuracy of the module related to that single class of information. Thus, the cited portion, "[a]n error minimization scheme ... to achieve better prediction accuracy" refers to a scheme for improving the accuracy of **a single class of information** and not methods for providing a method where a "combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually" as claimed.

Wu

As noted above, Wu is not prior art and therefore cannot be applied to sustain a rejection under 35 U.S.C. 103.

Tsumoto

Applicants respectfully submit that Tsumoto does not provide a method where a "combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually." The section on page 71 cited by the Examiner actually teaches away from Applicants' invention as claimed. In particular, "For example, let us consider a cases of a rule [age = 40-49] → m.c.h. Since $[x]_{[age = 40-49]} = (2,3,4,5)$ and D = {1,2,5,6}, **accuracy** and coverage are obtained as ... 0.5 and ... 0.5. Thus, if a person complains of a headache is 40-49 years old, then m.c.h is suspected, whose accuracy and coverage are equal to 0.5." [Emphasis added.]

Nearly identical reasoning is included at page 73, points 4.1 and 4.2. Applicants submit that this portion also provides for individual rule accuracies of 1.0 and a combined accuracy of 1.0.

Applicants note that the overall accuracy described on page 71 of 0.5 is exactly the same as the accuracy of the two rules individually (0.5 each). Similarly, the overall accuracy described on page 73 of 1.0 is exactly the same as the accuracy of the two rules individually (1.0 each). Thus, Tsumoto does not disclose or teach a method where a "combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually."

The Combinations of Sharpe, Barnhill, Kasabov and Tsumoto Do Not Render the Instant Claims Obvious

To support a rejection of the claims under 35 U.C.S. §103(a), "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences

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between the subject matter sought to be patented and the prior art are such that the **subject matter as a whole** would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." [Emphasis added.]

Thus, all elements of the claim must be taught, either explicitly or inherently by the prior art.

The Examiner has recited no sections of any of the prior art references that disclose the claim limitation, "the error of Combined Class A/Class B output is minimized and said combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually" as in claims 1, 3, and 23. Applicants cannot find any section of any of the prior art references that disclose the above limitation.

Moreover, the Examiner admitted that Sharpe, Kasabov, Barnhill, and Tsumoto, in any combination do not disclose or teach the limitation "combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually."

Nonetheless, the Examiner's overall conclusion was that somehow, the combination of cited references must teach the missing limitation. Applicants respectfully submit that at best, the Examiner's argument hinges on Wu. "It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the invention of Sharpe by calculating a combined class A/class B output with an error that is minimized and an accuracy that is greater than either class A or class B individually, as in claims 1, 3, and 23, or a Bayes process in claim 22, since Wu shows fusing individual outputs of classifiers to arrive at a consensus decision." Office Action, page 6 last paragraph.

However, Applicants submit that this reasoning must fail because Wu is not prior art.

Finally, even if the Examiner is correct that there is a motive present in the art to improve accuracy of diagnosis or prognosis based on a variety of different types of information, Applicants respectfully submit that none of the prior art, in any combination, disclosed or taught the invention as a whole as is required by 35 U.S.C. §103(a) as claimed. The Examiner has provided no evidence of either explicit or inherent disclosure of the missing element in any of the cited art.

If the Examiner wishes to present such evidence, Applicants invite the Examiner so submit a Declaration of a person of ordinary skill in the art. The only evidence in this case relating to what a person of ordinary skill in the art would derive from the cited references is the Kasabov reference.

For the rejection to be sustained, the Examiner must provide a "reasoned statement" of exactly how the combination of prior art references inherently teaches the above limitation. Such "reasoned statement" is not provided. Simply stating a motive to do so, without explaining how the missing element is rendered obvious, is insufficient.

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Comment on Examiners Responses to Arguments

Given that all of the Applicants' responses to prior rejections are "moot in light of the new grounds of rejection," Applicants believe that the prior responses were successful in overcoming the rejections.

The Kasabov Declaration was considered inapplicable to the issue of non-obviousness because "the Declaration asserts that the claimed invention results in improved accuracy [p.2, last ¶]. However, it is well settled that unexpected results must be established by factual evidence. Applicants have not presented any experimental data showing that the claimed process results in an unexpected result." Office Action page 8.

First, Applicants do not rest on a claim of "unexpected results." Applicants submit that once a computerized method is implemented, it will always have its expected effects. Rather, this invention is based on creation of new and non-obvious computer implemented methods for analyzing data.

Second, Applicants provided experimental data in the priority application (the 756 provisional) and in the instant application (International Filing Date: August 15, 2003). Disclosures of results of prior art methods and of the claimed invention are provided in the application as filed. The 756 application analyzed prior art data on page 2, first full text paragraph, wherein the prior art method "achieved 77.6% prognosis of both cured and fatal cases of B-cell lymphoma cancer." However, in the 756 application, page 5, second paragraph under "Example of the first approach," the Inventors showed that using the methods of the claimed invention, that "the combined model accuracy, ... gives an overall accuracy of 87.5%." Identical disclosures are present in the instant application as filed (see above). Please note that this represents a direct comparison of prior art and instantly claimed methods.

Thus, Applicants respectfully disagree with the Examiner's assertion that "Due to the absence of tests comparing applicant's claimed method steps with those of the closest prior art, applicant's assertion of unexpected results constitutes mere opinion evidence." As noted herein, Applicants submit that even if a motive was provided to do so, none of the cited art provides sufficient teaching of exactly **how to analyze data** where a "combined Class A/Class B output has greater accuracy than either Class A output or Class B output individually." Rather, the non-obviousness of the claimed invention is due to the non-obvious creation of methods to accomplish this heretofore unsolved problem.

This REPLY is being filed within two (2) months of the mailing date of the Office Action, and neither a Petition for Extension of Time nor a fee is required.

Applicants therefore respectfully request that this amendment be entered into the application, that the Examiner reconsider the current rejections, withdraw the finality of the rejections, find the claims allowable, and issue a Notice of Allowance.

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The Commissioner is authorized to deduct from or refund to Deposit Account No: 50-4089 any fee in connection with this REPLY.

If the Examiner believes that a telephonic interview with the undersigned would be useful in moving this application forward, the undersigned cordially invites such an interview.

Respectfully submitted,

Date: _____ August 3, 2009 _____ By: _____

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